POSTER SESSION

1052 Stent Results: Effect of Inflammation

Sunday, March 17, 2002, 3:00 p.m.-5:00 p.m.
Georgia World Congress Center, Hall G
Presentation Hour: 3:00 p.m.-4:00 p.m.

1052-6 Immunosuppressive Therapy for the Prevention of Restenosis After Coronary Artery Stent Implantation (IMPRESS Study)

Francesco Versaci, Achille Gaspardone, Fabrizio Tomai, Paolo Russo, Igino Proietti, Anna S. Ghini, Flavio Ribichini, Anna De Fazio, Luigi Chiariello, Pier A. Gioffrè, Filippo Crea, *Cattedra di Cardiochirurgia – Università Tor Vergata, Rome, Italy, Divisione di Cardiologia, Ospedale S. Croce e Carle, Cuneo, Italy.*

Background: Inflammation plays a key role in the process of neointimal proliferation after stent implantation (SI) and persistent elevation of C-Reactive Protein (CRP) following successful SI predicts the risk of coronary events.
Methods: IMPRESS is a double-blind randomised, placebo-controlled study aimed at assessing the effects of prednisone on 6 months clinical and angiographic restenosis after successful SI in a selected group of patients (pts) with high CRP levels after the procedure. The inclusion criteria were documented angina pectoris, one or multiple vessel stenoses treated with successful SI and CPR ≤0.5 mg/dl before, and >0.5 mg/dl 72h after the procedure. Eligible pts were randomised to receive orally either placebo (n=41) or prednisone (n=41). The dosage of prednisone administrated was: 1 mg/Kg orally during the first 10 days; 0.5 mg/Kg from 11 to 30; and 0.25 mg/Kg from 31 to 45 days.
Results: The two groups were similar with respect to demographic, clinical or angiographic characteristics. The 6-month rates of event-free survival were 95% in the prednisone group and 63% in the placebo group (p=0.0001). The rates of restenosis were 7% in the prednisone group and 33% in the placebo group (p=0.0012). The late loss was significantly lower in prednisone than in placebo group (0.38±0.56 vs 0.84±0.64mm, p=0.0009).
Conclusions: Therapy with oral prednisone reduces angiographic restenosis and clinical events after SI in pts with high post-procedural CRP levels.

1052-7 Study of Antirestenosis With the Biodivysio Dexamethasone Eluting Stent (STRIDE): A Multicenter Trial

Xiaoshun Liu, Yanming Huang, Ivan De Scheerder, On behalf of the STRIDE Investigators, *University Hospitals Leuven, Leuven, Belgium.*

Background: Drug eluting stents have been proposed as an alternative approach to prevent in-stent restenosis. Pre-clinical work showed a reduced intimal hyperplasia in a porcine model using the Biodivysio Drug Delivery Phosphorylcholine coated stent loaded with a high dose dexamethasone (DEX). The aim of this study is to evaluate the acute safety and efficacy of the Biodivysio DEX eluting stent implanted in patients with de novo single vessel disease.
Methods: In this multicenter trial, 71 patients, 79% were male, average age 61.9 (range 42 - 82) from 8 study sites were included. Risk facters: 63% had hypercholesterolaemia, 56% had hypertension, 42% had a previous MI, 46% had two or more than two vessel diseases, 31% had lesion type B2 or C, 28% had unstable angina pectoris. One 11 mm, 15mm or 18mm long Biodivysio DD PC stent was immersed in a 15 mg/ml DEX solution, yielding a total DEX dose of 45 µg per mm stent before implantation. Minimal lumen diameter (MLD) and % diameter stenosis (DS) were measured before, immediately after stenting and at 6-month (m) follow-up (f-up). The primary endpoint of the study is 6m angiographic restenosis rate. The secondary endpoints are 30 days and 6m major adverse cardiac events (MACE) defined as death, MI, CABG & target vessel revascularization.
Results: All the stent implantations were successful. QCA: mean reference diameter: 2.95±0.52 mm, MLD: 1.03±0.35 mm, % DS: 64.75±11.81% and MLD and % DS after stent implantation was 2.47±0.46 mm and 15.47±7.17% respectively. There was one in hospital death due to stent thrombosis. MACE at 30 days: one non stent related cardiac death, one non Q wave MI and one non target vessel revascularization due to recurrence of angina pectoris. Until now 15pts had their 6m control angiogram, none had an in-stent restenosis.
Conclusion: This preliminary results show that implantation of a Biodivysio Dexamethasone eluting stent is safe and feasible. It seems a promising approach to prevent in-stent restenosis.

1052-8 Temperature of the Arterial Wall After Stent Implantation: The Role of Poststent Inflammation

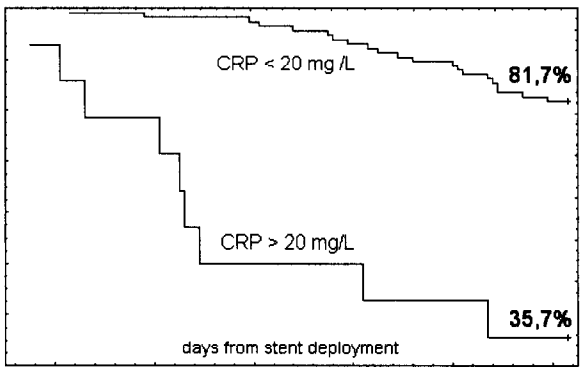
Leonidas D. Diamantopoulos, Huang Yanming, Liu Xiaoshun, Tony Flint, Ivan De Scheerder, Walter Desmet, Frans Van de Werf, *Cardiology Dept, UZ Gasthuisberg, Leuven, Belgium.*

Background: The temperature of the arterial wall has been succesfully corelated to its inflammation status. The purpose of this study was to investigate the inflammation status of the arterial wall after stent implantation.
Methods: For the purposes of the study, we catheterized 15 pigs with normal coronary arteries. Arterial wall temperature was studied with the ThermoSense coronary thermography system (Thermocore Medical Systems NV, Belgium) that uses a 4-thermistor catheter tip to record temperature. A 20mm long normal segment was selected at the proximal right coronary artery (RCA). Temperature was mapped in this segment via a continuous pullback (0,3mm/sec). Then a stent (Freedom stent, Global Therapeutics) was implanted in the same area, and the temperature scan was repeated once more for the same segment. Then, pigs were randomized in two groups for temperature scanning in the stented area: group A to be re-scanned after 5 days and then sacrificed, and group B to be re-scanned after 8 days and then sacrificed. Histology and local macrophage concentration was studied in all cases.
Results: The temperature of the arterial wall before the stent placement was equal to the adjucent areas. Immediately after stent placement, the stented area had slightly lower temperature than the adjucent areas (DT~0,1°C, p<0,01). 5 Days after the implantation, the stented area was significantly hotter than the adjucent areas (DT~0,15°C, p<0,01); histological examination showed the highest macrophage concentration at the place of the stent. At the ninth day these temperature differences were reduced to non-significant levels (DT~0,03°C, p=NS), and macrophage population was significantly lower.
Conclusions: Due to post-stent arterial wall inflammation, stented arterial segments show higher temperature around 5 days after implantation, while after 8 days these findings are reduced to almost normal levels.

1052-9 Comparison Between C-Reactive Protein Serum Levels and Mid-Term Stent Restenosis After Percutaneous Coronary Intervention

Giuseppe Calveri, Dajelli Ermolli N. Carlo, Bertelli Ylenia, Calco Salvatore, Uriarte Salerno A. Jorge, *"Circolo" Hospital, Varese, Italy, University of Insubria, Varese, Italy.*

BACKGROUND: Inflammation appears to play a pivotal role in the development of restenosis after coronary angioplasty and stent implantation (PTST). Thus serum acute phase reactants produced during the cathether-based procedure, such as C-reactive protein (CRP), may represent the expression of the inflammatory response induced by mechanical injury produced by deployed stent.
METHODS: 128 consecutive patients with acute coronary syndromes were subjected to elective PTST. CRP serum levels were measured after 24 hours from the invasive procedure. Further hospitalizations for recurrences of angina pectoris during six-month follow-up were angiographically tested for in-stent lumen narrowing (defined as >40% and >2 mm length of the previously implanted device).
RESULTS: At follow-up, patients with elevation of serum CRP >20 mg/L evidenced higher restenosis incidence (64,3% versus 18,3% p=0,0003) and mean stent survival was shorter (134,8 days versus 176,2 days p=0,006). In logistic regression, CRP>20 mg/L was related with higher risk of in-stent lumen narrowing (odds ratio 8,06 CI95% 2,39 - 27,20 p=0,0004).
CONCLUSIONS: In patients with acute coronary syndromes, elevated CRP levels after percutaneous coronary interventions were highly predictive of worse mid-term outcome of the implanted device.



1052-10 Carbon Coating Has No Effect on Inflammatory Response to Primary Stent Deployment

Mehmet E. Korkmaz, Egemen Tayfun, Haldun Muderrisoglu, Bulent Ozin, Aylin Yildirir, Melek Ulucam, *Baskent University, Ankara, Turkey.*

To investigate the effects of carbon-coated stents on inflammatory response we serially measured plasma levels of C-reactive protein (CRP), fibrinogen and cytokines (tumor necrosis factor, interleukins 1-beta, 6 and 8) in patients with single vessel coronary stenosis and without any inflammatory or infectious disease who underwent primary stent implantation.
Forty-six patients with single coronary lesions were included. Blood samples were obtained before and after 2, 4, 6, 24 and 48 hours after the procedure. In a randomized order, either an uncoated MAC (AMG Raesfeld-Erle, Germany) (UC-MAC) or a carbon-coated MAC (CC-MAC) stent was deployed without predilatation at a maximum pressure of 6 atmospheres for a duration of 90 seconds. If another inflation or a higher atmosphere is needed that patient was excluded.
Of the 46 patients (38 male, 8 female; age 55 ± 9) included. Fourteen had stable, 27 unstable 5 atypical angina. According to the ACC/AHA classification 35 lesions (76,1%) were type A, 10 (21,7%) type B and 1(2.2%) were type C. The mean size and length of the stents implanted were 2.98 ± 0.4 and 11.6 ± 3.7 mm respectively. Twenty-three CC-MAC stent and 23 UC-MAC stent were implanted to stenosis of 28 left anterior descending, 12 circumflex and 6 right coronary arteries.
Serum interleukin 6 (Il6) levels increased significantly in both CC-MAC and UC-MAC groups starting from 6 hours and returned to normal after 24 hours (from 3.0 ± 2 to 5.6 ± 3.8 to 6.3 ± 4.6 pg/ml, respectively in UC-MAC, from 3.7 ± 2.6, 6.3 ± 6.0 to 4.6 ± 3.7 pg/ml, respectively in CC-MAC) (p = 0.002). Plasma fibrinogen, CRP levels and leukocyte counts also increased in both groups (p < 0.05). There was no difference between the 2 groups in regard to IL6, CRP and fibrinogen increase. The percent increase in Il6, fibrinogen or CRP levels were not associated with the stent length, stent size or the clinical presentation (all p>0.05).
In conclusion stent implantation increases plasma interleukin 6, fibrinogen and CRP levels. This unfavorable inflammatory response seems not be affected by carbon coating.